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August 20, 2015

Via Hand Delivery

Ms. Meredith Laws
c/o Document Processing Desk
U.S. Environmental Protection Agency
Office of Pesticide Programs
MC: 7504P, Room S-4900
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Re: SenesTech, Inc., Registration Application for ContraPest®

Dear Meredith:

SenesTech, Inc. (SenesTech) is pleased to submit to the U.S. Environmental Protection Agency (EPA) the accompanying application to register its rodent contraceptive product, ContraPest®, EPA Reg. No. 901601-R. SenesTech thanks the Office of Pesticide Programs (OPP) for all of its efforts to support the product development and looks forward to working with OPP to bring ContraPest® to market.

As OPP knows, ContraPest® contains two new active ingredients: 4-Vinyl-1-cyclohexene diepoxide (VCD) and Triptolide. As part of this application, SenesTech supports unregistered sources of each of these new active ingredients. Memoranda from the OPP Hazard and Science Policy Council and the OPP Environmental Fate and Effects Division, along with copies of supporting references, are included in the accompanying volumes that address mammalian and environmental toxicity and fate data requirements, respectively, for the new active ingredients.

Consistent with the Registration Division's (RD) suggestion, SenesTech is filing an application initially for an indoor-only use product. SenesTech is on the schedule for contract laboratories to conduct testing that OPP may conclude is required, following further review, in support of outdoor uses. SenesTech plans to proceed with this testing unless OPP states these data are not needed, due to the low active ingredient concentrations in the end-use product or other reasons.



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SenesTech expects that OPP will place the registration application in Pesticide Registration Improvement Extension Act (PRIA 3) category R110, as discussed. SenesTech has paid 25 percent of the fee for two new active ingredients; a copy of the fee payment receipt is included in Volume 1. Also included in Volume 1 is SenesTech's petition for a fee reduction based on its status as a qualifying small business, with supporting documentation.

Attached to this letter is a Transmittal Document for the registration application, which identifies the 25 volumes included with this submission. The volumes address the product chemistry, mammalian and environmental toxicity and fate data requirements for the active ingredients and the end-use product. Also included in the submission are three references which, due to their size, are submitted as stand-alone volumes. Copies of other references are included as attachments within the volumes in which they are cited. Finally, four efficacy volumes are included in the submission. Two are from field trials that were made possible by OPP's determination that the studies were exempt from OPP's Experimental Use Permit requirements. SenesTech again thanks OPP as the information collected from these studies has informed product development significantly.

SenesTech looks forward to continuing to work with OPP in support of ContraPest®. If there are any questions or comments about this submission, please contact Elissa Calloway at (928) 863-7352 or elissa.calloway@senestech.com or Dr. Loretta Mayer at (928) 779-4143 or loretta.mayer@senestech.com or Dr. Cheryl Dyer at (928) 779-4143 or cheryl.dyer@senestech.com or Sheryl Lindros Dolan at The Acta Group, at (202) 266-5031 or sdolan@actagroup.com.

Sincerely,

Dr. Loretta Mayer

Attachments

cc: Mr. Mark Suarez (w/o attachments) (via e-mail)
Ms. Jacquelyn Marchese (w/o attachments) (via e-mail)
Ms. Sheryl Lindros Dolan

Transmittal Document

Name and Address of Submitter:

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3140 North Caden Court
Suite #1
Flagstaff, AZ 86004

Company No.: 91601
Contact Person: Elissa Calloway
Title: Vice President of Research
Telephone: (928) 779-4143
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Individual to be contacted, if necessary, to process this application:

The Acta Group
2200 Pennsylvania Ave., N.W.
Suite 100W
Washington, DC 20037

Contact Person: Sheryl L. Dolan
Telephone: (202) 266-5031
Fax: (202) 557-3836
E-Mail: sdolan@actagroup.com

Regulatory Actions:

End-use product registration application for ContraPest[®], a rodent contraceptive, supporting two new unregistered active ingredients. SenesTech anticipates that EPA will place this registration application in Pesticide Registration Improvement Extension Act (PRIA 3) category R110. An application for a small business fee reduction is included in Volume 1 of this submission. Also included in Volume 1 is a receipt for payment of 25 percent of the R110 fee for two new active ingredients.

Transmittal Date: August 20, 2015

List of Submitted Studies:

Vol.	Guideline No.	Study Report Title	MRID No.
1	Administrative	Registration Application for ContraPest [®] , Report No. 6002-001-01, August 20, 2015	
2	830.1550 830.1600 830.1620 830.1670 830.1900	Group A Product Chemistry for VCD, Report No. 6002-001-02, August 16, 2015	49700101
3	830.1700 830.1750	Preliminary Analysis and Certified Limits for VCD, Report No. 6002-001-03, August 14, 2015	49700102
4	830.1800	Enforcement Analytical Method for VCD, Report No. 6002-001-04, August 17, 2015	49700103
5	N/A	National Toxicology Program, Toxicology and Carcinogenesis Studies of 4-Vinyl-1-	49700104

Vol.	Guideline No.	Study Report Title	MRID No.
		cyclohexene Diepoxide (CAS No. 106-87-6) in F344/N Rats and B6C3F1 Mice (Dermal Studies). Natl Toxicol Program Tech Rep Ser., Nov. 1989, pp. 1-249, Report No. 6002-001-05, August 11, 2015	
6	N/A	Swern, Daniel, Organic Peroxides. Chemical Reviews. V45.1 p. 1-68 (1949); Report No. 6002-001-06, August 11, 2015	49700105
7	830.6302 830.7100 830.6303 830.7200 830.6304 830.7220 830.6313 830.7300 830.6314 830.7370 830.6315 830.7520 830.6316 830.7550 830.6317 830.7560 830.6319 830.7570 830.6320 830.7840 830.6321 830.7860 830.7000 830.7950 830.7050	Group B Product Chemistry for VCD, Report No. 6002-001-07, August 16, 2015	49700106
8	870.1100 870.4200b 870.1200 870.4300 870.1300 870.4100 870.2400 870.4200 870.2500 870.5100 870.2600 870.5300 870.3100 870.5375 870.3150 870.5385 870.3200 870.5395 870.3465 870.6200a 870.3700a 870.6200b 870.3700b 870.7485 870.3800 870.7800	Mammalian Toxicology for VCD, Report No. 6002-001-08 August 14, 2015	49700107
9	870.7485	Salyers, K.L., Disposition and Metabolism of 4-Vinyl-1-cyclohexene diepoxide in female Fischer 344 rats and B6C3F1 mice, University of Arizona, 1995; Report No. 6002-001-09, August 11, 2015	49700108
10	835.2120 870.7485 850.6100 850.2100 850.1010 850.1075 870.1100	Environmental Effects and Fate for VCD, Report No. 6002-001-10, August 13, 2015	49700109
11	830.1550 830.1600	Group A Product Chemistry for Triptolide, Report No. 6002-001-11, August 16, 2015	49700110

Vol.	Guideline No.		Study Report Title	MRID No.
	830.1620 830.1670 830.1900			
12	830.1700 830.1750		Preliminary Analysis and Certified Limits for Triptolide, Report No. 6002-001-12, August 16, 2015	49700111
13	830.1800		Enforcement Analytical Method for Triptolide, Report No. 6002-001-13, August 17, 2015	49700112
14	830.6302 830.6303 830.6304 830.6313 830.6314 830.6315 830.6316 830.6317 830.6319 830.6320 830.6321 830.7000	830.7050 830.7100 860.7200 830.7220 830.7300 830.7370 830.7520 830.7550 830.7560 830.7570 830.7840 830.7860 830.7950	Group B Product Chemistry for Triptolide, Report No. 6002-001-14, August 16, 2015	49700113
15	870.1100 870.1200 870.1300 870.2400 870.2500 870.2600 870.3100 870.3150 870.3200 870.3465 870.3700a 870.3700b 870.3800	870.4200b 870.4300 870.4100 870.4200 870.5100 870.5300 870.5375 870.5385 870.5395 870.6200a 870.6200b 870.7485 870.7800	Mammalian Toxicology for Triptolide, Report No. 6002-001-15, August 17, 2015	49700114
16	835.2120 870.7485 850.6100 850.2100 850.1010 850.1075 870.1100		Environmental Effects and Fate for Triptolide, Report No. 6002-001-16, August 7, 2015	49700115
17	830.1550 830.1600 830.1650 830.1670 830.1750 830.1900		Group A Product Chemistry for ContraPest®, Report No. 6002-001-17, August 18, 2015	49700116

Vol.	Guideline No.		Study Report Title	MRID No.
18	830.1700		Preliminary Analysis for ContraPest [®] , Report No. 6002-001-18, August 17, 2015	49700117
19	830.1800		Enforcement Analytical Method for ContraPest [®] , Report No. 6002-001-19, August 17, 2015	49700118
20	830.6302 830.6303 830.6304 830.6313 830.6314 830.6315 830.6316 830.6317 830.6319 830.6320 830.6321 830.7000	830.7050 830.7100 860.7200 830.7220 830.7300 830.7370 830.7520 830.7550 830.7560 830.7570 830.7840 830.7860 830.7950	Group B Product Chemistry for ContraPest [®] , Report No. 6002-001-20, August 17, 2015	49700119
21	870.1100 870.1200 870.1300 870.2400 870.2500 870.2600		Mammalian Acute Toxicology for ContraPest [®] , Report No. 6002-001-21, August 17, 2015	49700120
22	40 C.F.R. § 158.400		Dyer, C.A., Efficacy of ContraPest [®] to Induce Infertility in Sprague Dawley Rats, Report No. CPF029, July 2, 2015	49700121
23	40 C.F.R. § 158.400		Mayer, L., Management of Urban Rat (<i>Rattus norvegicus</i>) Populations with SenesTech Fertility Management Bait, Report No. NYC001, January 30, 2014	49700122
24	40 C.F.R. § 158.400		Mayer, L., Compromised Fertility in Free Feeding of Wild-Caught Norway Rats with a liquid bait containing 4-vinylcyclohexene diepoxide and triptolide, Report No. FTC001, June 17, 2015	49700123
25	40 C.F.R. § 158.400		Mayer, L., Management of Rural Norway Rat Populations on Pig Farms with SenesTech's Fertility Management Bait, Report No. MBP001, June 30, 2015	49700124